



# UNITED STATES PATENT AND TRADEMARK OFFICE

*ck*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,220	11/09/2001	Che-Kun James Shen	514162000120	5165
20872	7590	02/10/2006	EXAMINER	
MORRISON & FOERSTER LLP 425 MARKET STREET SAN FRANCISCO, CA 94105-2482			KAUSHAL, SUMESH	
			ART UNIT	PAPER NUMBER

1633

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/014,220

Applicant(s)

SHEN, CHE-KUN JAMES

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1633

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 13 January 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 21-34.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☒ Other: See Continuation Sheet.

  
SUMESH KAUSHAL Sumesh Kaushal  
PATENT EXAMINER Primary Examiner  
Art Unit: 1633

Continuation of 11. does NOT place the application in condition for allowance because: Claims 21, 23-27 and 30-32 stand rejected under 35 U.S.C. 102(b) for the same reasons of record as set forth in the office action mailed on 10/19/05. The applicant's response filed on 01/13/06 has been fully considered. The declaration filed on 1/13/06 has not been considered because the contents of this document is not legible possibly due unacceptable quality of photocopy provide by the applicant. However in the remarks submitted on 1/13/06 the applicant argues that applicants are not aware of any art that would support the assertion that a construct in a transient transfection assay in human cells would integrate with sufficient frequency to produce an isolated animal cell as presently claimed. However on the contrary the applicant also asserts that integration into mammalian cells such as human cells occurs at very low frequency (see Dr. James Shen declaration submitted 01/12/03). In further contradiction to applicants own assertion the applicant argues that the random integration would not have occurred with in the time period of transient transfection assay, therefore Zhang 1995 does not anticipate the invention as claimed. But in further contradiction the applicant also believes that the construct might have integrated in small fractions of cells, which would be hardly considered isolated within the scope of instant claims. However, applicant's arguments are found not persuasive, especially in view of evidence provided by applicant's earlier declaration that "the construct might have integrated in small fractions of cells" (see Dr. James Shen declaration submitted 01/12/03). Furthermore the scope of isolated cells as claimed in the instant application encompasses cells isolated from an animal and not isolated to homogeneity in context to the chromosomal integration of the transgene. Thus given the broadest reasonable interpretation the cited art clearly anticipate the invention as claimed which inherently teaches isolated animal cells having chromosomal integration of the transgene (see Dr. James Shen declaration submitted 01/12/03 especially page-2).

Claims 22, 28-29 and 33-34 stand rejected under 35 U.S.C. 103(a) for the same reasons of record as set forth in the office action mailed on 10/19/05. The applicant argues that the chromosomal integration of SEQ ID NO:1 (TCTGAGTCA) show superior and unexpected results as shown in table-1 of the specification. The applicant further argues that see Dr. James Shen declaration submitted 01/12/03 provided abundance evidence that DNA element that provides position independent expression across the animal kingdom, therefore the invention as claimed is an unexpected result. In addition The applicant argues that Zhang 1995 does not teach an isolated animal cell whose genomic DNA comprises at least one copy of chromosomally integrated transgene. However, applicant's arguments are found not persuasive because the position independent expression across the animal kingdom is not an unexpected finding, since the cited art clearly teaches that HS-40 enhancer element is capable of expressing in variety of cells types i.e. K562, MEL and HeLa cells. In addition, as stated above the cited art inherently teaches isolated animal cells having chromosomal integration of the transgene (see Dr. James Shen declaration submitted 01/12/03 especially page-2). Thus the invention as claimed is prima facie obvious in view of cited prior art of record. .

Continuation of 13. Other: The declaration filed on 1/13/06 has not been considered because the contents of this document is not legible possibly due to an unacceptable quality of photocopy provided by the applicant..